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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,715	04/25/2001	Herwing Janssen	00-40374-US	6268

7590

01/27/2003

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

841715

Applicant(s)

JANDSEN et al

Examiner

MOLLEY

Group Art Unit

1416

11

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/29/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-23, 25 & 26 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 25 is/are allowed.
- ☒ Claim(s) 1-23, 26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 8410
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Receipt is acknowledged of IDS (8/19/02) amendment of 10/28/02 and IDS of 11/8/02, an apparent Duplicate of the originally entered amendment was also received, (10/28) but was not entered, as the claims do not indicate "amended twice". Still a third, and 4th copy were received, again, not entered, on 10/29/02.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-23, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of record is maintained, to the following extent. The rejection to long chain is maintained, as no definition is present, and examples are at 16 carbons, but, 5, 6, 7 may be construed as Long - if ~~in fact~~, 16 is minimal, we see support as suggested by the phrase including 16 c, at P.16. They're ~~in~~ no spinosad, spinosyn A, spinosyn D, or any component produced by ~~S. spinosa~~, (~~Saxchara-spinosa~~ ^{spinosad}) in claim 1. Therefore, claim 3 has no antecedent basis. Finally, please reconsider amending claim 1 "R" is not an action this examiner is familiar with, in this formula. There is no antecedent in claim 1, for claims 4, 5, 6, 7. Please insert the specification of Spinosad, spinosyn A, D and R in claim 1; and drops the "any component-", as that language would not seem to constitute any structural form within the confines of the claimed structure as drawn. "Any component", would constitute a patentably distinct species separate from the identified structure. In claim 26, no ranges are given/ trace amounts

of everything, in any vehicle, for any purpose, would be permissible, and is not definitively claiming the instant invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The will maintain this rejection, in spite of difference to applicant's arguments, because testing each and every one of the "any component – at least quantitatively, an excessive amount of experimentation, requiring both adult and nit determination of unstated levels of lethality for each component.

Claims 1-10, 12-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Snyder - 6063771.

The rejection of record is maintained applicant has not declared Snyder to be the instant inventor, or 6063771 take of the instant assignee.

See col. 14, Bn Snyder was aware of the use of solvents for spinosyns; the instant composition are included in Snyder's array of composition, all suitable for adult lice and nit destruction – Snyder also Looks for their removal (col. 14, lines 40-43) and adds advantageous optional hair care ingredients (as at col. 14, C).

Applicant's arguments filed 1/28/02 have been fully considered but they are not persuasive. Applicant argues Snyder is for dispersions, not solutions, but the Snyder compositions mimic those as claimed, of the instant invention, and include solvents. Snyder also is non-limiting advantageous formulations permit of hair care, in addition to good riddance of line. We would argue the lach of solution, of alcohol with water – we

would see applicant's formulations as emulsions or dispersions. See claim 13, to particular.

Claims 1-9, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boeck et al – EP 0375316.

Insecticide spinosyns, including A and B are disclosed (Page 3, line 14+) with solubility in alcohols – (p. 17, line 36+) with other components of *Sacch spinosa*, in solution (p. 46, lines 15-25) if desired – for topical ecto parasites (lice are ecto parasite) control. This meets the compositions as instantly claimed, regardless of intended use see Example 13, D. Toximal & stabilizers maybe used (p.28, bottom).

Claims 1-7, 9, 10, 12-~~16~~, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kassebaum- WO 01/12156.

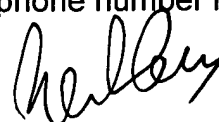
Ectoparasiticial levels of spinosyn (.01-25%) in solvent systems for topical application are taught, with the instant non-specific "stabilizing" agent, a long chain fatty acid ester, isopropyl myristate (p.2). The spinosyns are A, D, spinosad and fermentation products of *5. spinosa* (page 4, line 15-20). Additives are stabilizers, antioxidants, viscosity modifiers, and other carriers, excipients, adjuvants (p.7, lines 24-28) art recognized. Solvents include benzyl alcohol (p.7, lines 20-23), 0.26% spinosad was very effective to kill lice (Table II). Additional instant stabilizers are seen as acids (p.6, bottom). These are at .61% (Example 4, a)) also seen as pH adjusters. Propylene glycol may also be present, as are emulsifier, limonene, and emulsion stabilizers, n-methyl pyrrolidone with conditioners, triacetin (p.10).

Applicant's arguments filed 10/29/02 have been fully considered but they are not persuasive. Applicant's arguments, to the extent persuasive, have resulted in withdrawal of rejections, but, Examiner finds Snyder to be the same as applicant invention – lice treatment with spinosad S and D, in some of the same compositions as are claimed, while Boeck and Kassebaum also exemplify known use of spinosad, with use of the same and similar adjuvants although the applicant's Vehicle formulation is known in the topical application/ cosmetic arts, shown by examiner and by applicant, in regard to the Mencke and Reid. Insecticidal topical compositions, no recognition of solvating spinosad is disclosed, and without recognition of the low levels required to provide efficacy, examiner questions whether one would be motivated to cobble together the particular amounts of adjuvants applicant utilizes in order to provide an acceptable, less toxic nit and Louse Killer applicable to human use, as of applicant's claim 25.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703)308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



NEIL S. LEVY
PRIMARY EXAMINER